PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS

AND INTERFERENCES

Ex parte Hlavka et al.

Appeal No. _____

Serial No.:	10/622,207
Filed:	July 18, 2003
Art Unit:	3774
Examiner:	William H. Matthews
Inventor:	Edwin J. Hlavka et al.
Title:	METHOD AND APPARATUS FOR PERFORMING CATHTER-BASED ANNULOPLASTY
Attorney Docket:	MICO-06C
Confirmation No.:	4023

Cincinnati, Ohio 45202 December 9, 2008

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

This brief is in furtherance of Appellants' Notice of Appeal filed December 2, 2008, appealing the decision of the Examiner dated September 2, 2008, finally rejecting claims 60-67 and 69 (all pending claims). A copy of the claims appears in the Claims Appendix to this brief.

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I. Real Party in Interest

The real party in interest is Mitralign, Inc. of New York, New York, which is the assignee of the present invention.

II. Related Appeals and Interferences

There are no related appeals or interferences known to the Appellants or the Appellants' legal representative that will directly affect, or be directly affected by, or will have a bearing on the decision of the Board in the present Appeal.

III. Status of Claims

Claims 60-67 and 69 were pending in the Application after the final rejection dated September 2, 2008, and were rejected under 35 U.S.C. §112, first paragraph. Claim 69 was subsequently cancelled in an after-final amendment filed October 30, 2008. Claims 60-67 are subject to this appeal.

IV. Status of Amendments

An after-final amendment was filed October 30, 2008, cancelling claim 69. This amendment was entered.

V. Summary of Claimed Subject Matter

Claim 60 is the only independent claim. Below, Appellants have provided a summary of the claim language mapped to the supporting disclosure of the exemplary embodiments for representation purposes only.

Claim 60 is directed to a device for use in a catheter-based annuloplasty procedure on a heart valve 1128, including three or more non-plicating fasteners 1012, 1112 configured to be individually fixed to tissue 970, 1170 adjacent the annulus of the heart valve at spaced locations by piercing the tissue without plicating the tissue at the spaced locations. (Application at p. 15, lines 3-11.) The device further includes at least one catheter 1004 having a lumen capable of delivering and inserting the plurality of non-plicating fasteners 1012, 1112 into the tissue adjacent the annulus. (Application at p. 14, line 29 – p. 15, line 3.) An elongate tensioning element 1140 is coupled with the non-plicating fasteners 1012, 1112 and is configured to be tensioned by pulling on only one end thereof to place the plurality of non-plicating fasteners 1112. 1012 in an activated state positioned closer together to plicate the tissue between the fasteners 1112, 1012. (Application at p. 15, line 29 – p. 16, line 4.) A locking feature is operative to fix the plurality of non-plicating fasteners in the activated state. (Application at p. 16, lines 2-5.)

VI. Grounds of Rejection to be Reviewed on Appeal

A. The rejections of claims 60-67 under 35 U.S.C. §112, first paragraph.

VII. Argument

A. The Rejections of Claims 60-67 Under 35 U.S.C. §112

Claims 60-67 stand rejected under 35 U.S.C. §112, first paragraph, with respect to the recitation of "three or more non-plicating fasteners configured to be individually fixed to tissue adjacent the annulus of the heart valve," and "an elongate tensioning element coupled with the non-plicating fasteners," as recited in claim 60. Claim 60 is the only independent claim of this rejected group, and is directed to a device for use in a catheter-based annuloplasty procedure on a heart valve, the device comprising:

> three or more non-plicating fasteners configured to be individually fixed to tissue adjacent the annulus of the heart valve at spaced locations by piercing the tissue without plicating the tissue at the spaced locations;
>
> at least one catheter having a lumen capable of delivering and inserting the plurality of non-plicating fasteners into the tissue adjacent the annulus;
>
> an elongate tensioning element coupled with the non-plicating fasteners and configured to be tensioned by pulling on only one end thereof to place the plurality of non-plicating fasteners in an activated state positioned closer together to plicate the tissue between the fasteners; and
>
> a locking feature operative to fix the plurality of non-plicating fasteners in the activated state.

Appellants respectfully traverse the rejection of claim 60 under 35 U.S.C. §112, first paragraph, because the Application describes the invention in sufficient detail that persons skilled in the art would understand that the Appellants had possession of the claimed invention, and would understand how to make and use the claimed invention, based on the application disclosure.

"The written description requirement of 35 U.S.C. §112, first paragraph, is separate from the enablement requirement found in the same provision of 35 U.S.C. §112. . . . Satisfaction of the 'written description' requirement does not require *in haec verba* antecedence in the originally filed application." Staehelin v. Secher, 24 USPQ2d 1513, 1519 (BPAI 1992). "Adequate description under the first paragraph of 35 U.S.C. §112 does not require literal support for the claimed invention. . . . Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed." Ex parte Parks, 30 USPQ2d, 1234, 1236-37 (BPAI 1993). "To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." See, e.g., Moba, B.V. v. Diamond Automation, Inc., 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); Vas-Cath, Inc. v. Mahurkar, 19 USPQ2d at 1116 (Fed. Cir, 1991). "The Examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the original disclosure a description of the invention defined by the claims." MPEP §2163(II)(A)(3)(b).

"The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." In re Buchner, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). The Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. See, In re Wright, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

> [T]he first paragraph of 35 U.S.C. 112 . . . requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons or ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws.

In re Fisher, 166 USPQ 18, 24 (CCPA 1970).

"It is a familiar principal of patent law that a claim need not be limited to a preferred embodiment." Lampi Corp. v. American Power Prods., Inc., 56 USPQ2d 1445,1455 (Fed. Cir. 2000). "The disclosure as originally filed need not provide *in haec verba* support for the claimed subject matter." Id. Rather, Applicants are entitled to claim as broadly as the prior art and their disclosure will allow. In re Rasmussen, 650 F.2d 1212, 1214 (CCPA 1981).

The Application at page 15, line 23, through page 16, line 4, describes how fasteners (e.g., T-Bars 1112) are coupled with the tensioning element 1140 by way of the implant 1124. Specifically, the T-Bars 1112 secure the implant 1124 to the tissue, and the tensioning element 1140 is inserted within the implant 1124. The implant may thereafter be shortened by applying tension to tension element 1140 to thereby reduce or eliminate a gap between the leaflets of a mitral valve, as described in the Application at page 16, lines 6-13. Accordingly, Appellants assert that persons of ordinary skill in the art would understand that Appellants had possession of the invention set forth in claim 60 based on the disclosure, including page 15, line 23, through page 16, line 4, and FIGS. 11A, 11B. Moreover, persons of ordinary skill in the art would certainly be able to

make and use the invention set forth in claim 60 based on the disclosure, including the passages noted above.

In rejecting the claims under 35 U.S.C. §112, first paragraph, the Examiner has failed to explain how or why persons skilled in the art would not recognize a description of the claimed invention, or how or why persons skilled in the art would not understand how to make and use the claimed invention. Moreover, the Examiner admits that the term "'coupled' broadly encompasses both a direct and indirect connection." (Advisory Action dated November 14, 2008, at continuation sheet.) The Examiner further states that "[t]he specification only provide [sic] support for indirect coupling, therefore the claim limitation is considered new matter." Id. Accordingly, the Examiner concedes that claim 60 is specifically supported by the Specification, at least with respect to an indirect connection.

Appellants respectfully traverse the Examiner's new assertion that the term "coupled" adds new matter. Appellants are entitled to claim as broadly as is reasonably supported by the Specification, and are not limited to what is disclosed in a single embodiment of the Specification. The Application describes the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the Appellants had possession of the claimed invention, as discussed above. Moreover, nothing in the Application indicates that Appellants intended to be limited to the particular embodiments disclosed. On the contrary, the discussion of how fasteners (T-Bars 1112) are coupled with the tensioning element 1140 is described in the Application as being "one method of providing tension to an implant." (Application at p. 15, lines 23-24.) At page 16, lines 20-

21, the Application states that "[i]t should be appreciated that the configuration of tensioning element 1140 be different than shown herein."

For at least the reasons discussed above, Appellants assert that claim 60 is supported by the Specification and does not add new matter. Accordingly, Appellants respectfully request that the rejections of claim 60 under 35 U.S.C. §112, first paragraph, be reversed.

Claims 61-67 each depend from independent claim 60 and are therefore in condition for allowance for at least the reasons discussed above with respect to claim 60. Accordingly, Appellants respectfully request that the rejections of claims 61-67 under 35 U.S.C. §112, first paragraph, also be reversed.

Conclusion

For the reasons discussed above, Appellants respectfully urge the Board to reverse the rejections of claims 60-67.

If there are any questions regarding the foregoing, please contact the undersigned at (513) 241-2324. If any charges or credits are necessary to complete this communication, please apply them to Deposit Account 23-3000.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

1-59. (CANCELED)

60. (PREVIOUSLY PRESENTED) A device for use in a catheter-based annuloplasty procedure on a heart valve, the device comprising:

three or more non-plicating fasteners configured to be individually fixed to tissue adjacent the annulus of the heart valve at spaced locations by piercing the tissue without plicating the tissue at the spaced locations;

at least one catheter having a lumen capable of delivering and inserting the plurality of non-plicating fasteners into the tissue adjacent the annulus;

an elongate tensioning element coupled with the non-plicating fasteners and configured to be tensioned by pulling on only one end thereof to place the plurality of non-plicating fasteners in an activated state positioned closer together to plicate the tissue between the fasteners; and

a locking feature operative to fix the plurality of non-plicating fasteners in the activated state.

61. (PREVIOUSLY PRESENTED) The device of claim 60, wherein the tension placed on the tensioning element is continuously adjustable.

62. (PREVIOUSLY PRESENTED) The device of claim 60, further comprising a guide wire received in the catheter, said guide wire having an anchoring tip capable of being fixed to the tissue adjacent the annulus to maintain a position within the left ventricle.

63. (PREVIOUSLY PRESENTED) The device of claim 60, wherein the locking feature forms a part of the tensioning element.

64. (PREVIOUSLY PRESENTED) The device of claim 63, wherein the locking feature is formed by tying off the tensioning element.

65. (PREVIOUSLY PRESENTED) The device of claim 60, wherein a distal tip of the catheter is steerable.

66. (PREVIOUSLY PRESENTED) The device of claim 60, further comprising an expandable member deliverable through a catheter and capable of being expanded against the tissue adjacent the annulus during insertion of the plurality of non-plicating fasteners.

67. (PREVIOUSLY PRESENTED) The device of claim 60, wherein said at least one catheter further comprises a delivery catheter configured to deliver and insert the plurality of non-plicating fasteners.

68-70. (CANCELED)

IX. EVIDENCE APPENDIX

None

X. RELATED PROCEEDINGS APPENDIX

None